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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/450,217	11/29/99	ERDMANN	P 8265-296-999

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EXAMINER

LUKTON, D

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1653

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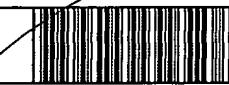
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/450,217	Applicant(s) Erdmann
Examiner David Lukton	Group Art Unit 1653



Responsive to communication(s) filed on Oct 11, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-22 is/are pending in the application.  
Of the above, claim(s) 14-22 is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 1-13 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Pursuant to the directives of paper No. 7 (filed 10/11/00), claim 2 has been amended.

Claims 1-22 remain pending, of which claims 14-22 remain withdrawn from consideration.

Applicants' arguments filed 10/11/00 have been considered and found persuasive in part.

The previously imposed §103 rejection over Etzel is withdrawn.

\*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites "removing cations from a lactic raw material...to obtain a pH of 1-4.5" First, how does one remove cations without also removing anions? It is not possible to have a solution of anions only. One can, of course, remove cations from solution, while at the same time providing cationic moieties (at least one cation for each anionic amino acid residue present in the protein), such as protonated amino groups, that are bonded to a solid phase support. But this is not "removal" *per se*, so much as "displacement" (of soluble cations by resin-bound cations). It is also possible to remove both cations and anions

(both of low molecular weight) by dialysis or ultrafiltration. But it is not possible, as claim 1 implies, to simply remove cations from solution so as to generate a solution of anions.

\*

Claims 1-13 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "removing cations from a lactic raw material". This implies that it is possible to remove cations without also removing anions, i.e., to generate a solution of anions. If consistent with intentions, one of the following could be used:

*23a. A process ... comprising*

- a) deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material,*
- b) adjusting the pH to within the range of 1-4.5,*
- c) contacting the substantially deionized lactic raw material with an anionic resin...etc.*

*23b. A process ... comprising*

- a) removing ions from a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material,*
- b) adjusting the pH to within the range of 1-4.5,*
- c) contacting the substantially deionized lactic raw material with an anionic resin...etc.*

*23c. A process ... comprising*

- a) adjusting the pH to within the range of 1-4.5*
- b) adsorbing the proteins present in the lactic raw material to a cation exchange column,*
- c) washing with buffer to remove ions and thereby obtain a substantially deionized lactic raw material,*
- d) contacting the substantially deionized lactic raw material with an anionic resin...etc.*

Claim 11 is indefinite in several respects. First, the claim recites "further comprising". However, this would tend to signify an additional step, which is not the case. Second, the claim recites "lactic raw material" (abbreviated "LRM"), which leaves open the question of whether the deionized form, or the pre-deionized form is intended. Third, the range cited is "about" 1:1 to "about" 1:30. The cited range is mathematically equivalent to a range of 50%-97% (by volume) of the LRM (as a percent of LRM + resin). But recitation of the qualifier "about" leaves open the question of the actual lower and upper limits. Is the lower limit of the lactic raw material 50% by volume, or is it some lower amount; is the upper limit of the lactic raw material 97% by volume or is it some higher amount...? The following could be used:

*The process according to claim 1 wherein the anionic resin and the deionized lactic raw material are present in a ratio by volume of between 1:1 and 1:30.*

\*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3 and 5 are rejected under 35 U.S.C. §103 as being unpatentable over Shimatani (USP 5,434,250).

Shimatani teaches (beginning at col 2, line 67) a process of obtaining GMP by passing desalted whey, at acidic pH, through a cation exchanger. Additionally, claim 5 of the patent (col 6, line 23+) teaches a process of obtaining GMP by passing whey, at acidic pH, through a cation exchanger, and then employing the further step of ultrafiltration. (The instant claims do not preclude an ultrafiltration step).

The reference does not equate "cation exchanger" with "anionic resin", but skilled chromatographers know these to be the same. Thus, the claims are rendered obvious.

\*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1630